## Effects of the Trauma Collaborative Care Intervention: 12-Month Results from a Prospective Multicenter Cluster Clinical Trial

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**Purpose:** Our objective was to evaluate the impact of the Trauma Collaborative Care (TCC) program on 1-year outcomes. TCC was developed to improve early psychosocial sequelae of orthopaedic trauma and includes the Trauma Survivors Network (TSN) and additional collaborative care services. Prior results showed that there was a small benefit to TCC program recipients, at 6 weeks post injury, compared to controls and our hypothesis is that there would be a benefit at 12 months from injury.

Methods: The study design was a prospective, multicenter, cluster clinical trial at 6 Level I trauma centers. The study included patients with high-energy orthopaedic injuries requiring surgery and hospital admission: 378 patients at 6 trauma centers implementing the TCC program, and 344 patients at 6 trauma centers receiving usual care. The TCC early intervention included patient education, peer visits, and coaching calls. The main validated outcome measures were the Short Musculoskeletal Function Assessment (SMFA), Patient Health Questionnaire 9 (PHQ-9), and Posttraumatic Stress Disorder (PTSD) Checklist (PCL). The primary outcome was a composite outcome defined to be positive if SMFA Dysfunction Index >18.2 or SMFA Bother Index >23.7 or Depression (PHQ-9) >9 or PCL >35. A 2-stage Bayesian hierarchical statistical procedure was used to characterize treatment effects under an intention-to-treat and full intervention model. 28% of patients received incorrect recommendations for action on one of seven items in their 6-week risk assessment. Sensitivity analyses did not suggest this error altered our conclusions.

**Results:** The posterior estimates of the intention-to-treat effect (odds ratio scale) for all five end points suggest the intervention did not affect outcomes. The effect of treatment on the composite end point was 1.05 (95% confidence interval [CI]: 0.60-1.63); SMFA dysfunction >18.2 0.99 (0.55-1.53); SMFA bother >23.7 0.95 (0.57-1.45); PHQ-9 >9 1.27 (0.72-1.96), and PCL >35 1.16 (0.66-1.81). The posterior probabilities that the TCC program had a beneficial treatment effect were as follows: composite outcome (43%), SMFA bother index (59%), SMFA dysfunction index (25%), depression (14%), and PTSD (30%). The estimated effect of receiving the intervention was similar under both the intention-to-treat and full receipt models of analysis. Substantial variation existed across the 6 intervention sites in utilizing intervention component with only 29% of intervention patients receiving all 5 components.

**Conclusion:** Despite showing early positive effects and in contrast to our hypothesis, results of this analysis suggest the TCC as delivered had no effect on 1-year outcomes among these patients.